IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9193

Bartle, J. January 9, 2014

Randall D. Herman ("Mr. Herman" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Rayna Herman, Mr. Herman's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.[4] See Settlement Agreement §§ IV.B.1.a. & I.22.

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

In January, 2011, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Winston Gandy, M.D. Based on an echocardiogram dated April 14, 2003, Dr. Gandy attested in Part II of claimant's Green Form that Mr. Herman suffered from mild aortic regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[5] Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of $915,492.[6]

In the report of claimant's echocardiogram, the reviewing cardiologist, Azam Ansari, M.D., F.A.C.C., stated that claimant had mild aortic regurgitation "compromising 16% ... in the [parasternal] long axis view." Under the definition set forth in the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal

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5. Dr. Gandy also attested that claimant suffered from mild mitral regurgitation, bacterial endocarditis associated with either mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a). As the Trust concedes that Mr. Herman underwent surgery to replace his aortic valve, the only issue is whether he is eligible for benefits.

to or greater than ten percent (10%) of the left ventricular outflow tract height ("LVOTH"). Settlement Agreement § I.22.

In March, 2011, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Parmar determined that there was no reasonable medical basis for Dr. Gandy's representation that Mr. Herman had mild aortic regurgitation because his echocardiogram demonstrated only trace aortic regurgitation.[7] Specifically, Dr. Parmar explained, "The [aortic regurgitation] is trace by Singh criteria in my opinion. The [aortic regurgitation] is just about 1cm below the [aortic valve] and the [aortic regurgitation] width/LVOT is less than 5%."

Based on the auditing cardiologist's finding that Mr. Herman did not have at least mild aortic regurgitation, the Trust issued a post-audit determination denying Mr. Herman's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, Mr. Herman argued that the auditing cardiologist failed to recognize areas within the

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7. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace aortic regurgitation is defined as a JH/LVOTH ratio of less than 10%.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Herman's claim.

echocardiogram where mild aortic regurgitation was present and review all records supplied to him. In support, claimant submitted a declaration of Ethan J. Podet, M.D. Dr. Podet stated, in pertinent part, that:

> 4. Based upon an independent review of additional records including an echocardiogram (CD images, data and report) dated April 14, 2003 and operative record dated April 7, 2006 I hereby render and submit the following opinions ....
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> a. I find a reasonable medical basis for the Yes response given by Dr. Winston Gandy's Question at Issue C3B and finding of Mild Aortic Insufficiency on the April 14, 2003 study.
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> b. My remeasurement of Aortic Insufficiency (AI) location and time stamp on the April 14, 2003 video are detailed on my worksheet, as follows: (AI) Jet/LVOT Diameter ratio: .23cm/2.3cm @ 0:18:56 = 10%, .37cm/2.2cm @ 0:19:11:21 = 17%, TECH'S LVOT measurement @0:19:18=2.2cm. Therefore, AI Jet: LVOT Diameter ratio equals or exceeds 10% = Mild AI by Green Form Criteria.
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> c. See also, AI visible in 3 chamber view at 0:22:03:26 and is representative of aortic regurgitation present on the study dated April 14, 2003.
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> d. My expert opinion is based on Singh criteria.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Parmar submitted a declaration in which he again concluded

that there was no reasonable medical basis for the attesting physician's finding that Mr. Herman had mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Dr. Parmar stated, in relevant part, that:

> 10. Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant had mild aortic regurgitation.
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> ....
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> 12. With respect to aortic regurgitation, at Contest, I reviewed the entirety of Claimant's April 14, 2003 echocardiogram study, as well as those specific points identified by Dr. Podet. The frames identified by Dr. Podet include measurements made on the study by the [echocardiogram] technician, which [are the] measurements Dr. Podet relies upon. However, the measurements at these frames (0:18:56, 0:19:18, 0:19:11:21, and 0:22:03:26) are inaccurate. Dr. Podet states that AI is seen at frame 0:18:56, measuring 0.23 cm, and at frame 0:19:11:21, measuring 0.37 cm (as measured by the [echocardiogram] technician). Both of these measurements are overestimated - in each case, the measurement is taken below the aortic valve, where the aortic regurgitation jet appears wider than it does if it were properly measured, at the level of the aortic valve. These frames do not demonstrate mild aortic regurgitation.
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> 13. The [echocardiogram] technician also made *accurate* measurements of [aortic regurgitation] at frame 0:19:07, at 0.107 cm. I agree with this measurement. Moreover, I made measurements of the [aortic regurgitation] width in the parasternal view measuring 0.1 cm. The technician measured the LVOT at 2.2 cm, which I also agree with. Based on my

> measurements and based on the *accurate* measurements of the echocardiographic technician made during this echocardiogram, the [aortic regurgitation] is trace. It does not meet the criteria for mild [aortic regurgitation], as the AR/LVOT width is below 10%. After extensive review of the medical records and echocardiograms as noted above, there is no reasonable medical basis to conclude that the April 14, 2003 echocardiogram demonstrates mild aortic regurgitation - aortic regurgitation is only trace by the Singh criteria.

The Trust then issued a final post-audit determination, again denying Mr. Herman's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why his claim should be paid. On November 29, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8711 (Nov. 29, 2011).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 2, 2012, and claimant submitted a sur-reply on April 11, 2012. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for the attesting physician's finding that he suffered from at least mild aortic regurgitation on an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Herman reasserts the arguments made in contest. Claimant also argues that the difference between trace and mild aortic regurgitation "is virtually insignificant to a treating Cardiologist" and that if the auditing cardiologist was able to eyeball trace aortic regurgitation there is a reasonable medical basis for a finding of mild aortic regurgitation. Finally, claimant notes that the echocardiogram on which his claim is based was performed in the Trust's Screening Program.

In response, the Trust argues that claimant did not establish a reasonable medical basis for Dr. Gandy's representation of mild aortic regurgitation because Dr. Parmar disputed that each of the frames identified by Dr. Podet were demonstrative of mild aortic regurgitation or representative of the aortic regurgitation seen on the study. In addition, the Trust asserts that Dr. Parmar was not required to measure claimant's level of aortic regurgitation.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Herman had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Specifically, Dr. Vigilante explained:

I reviewed the tape of the Claimant's echocardiogram of attestation. The Claimant's name and date of April 14, 2003 were documented on this study.... All of the usual echocardiographic views were obtained. However, the study was not performed in accordance with the usual standards of care. The Nyquist limit was set too low at 53 cm per second at a depth of 16 cm in the parasternal long axis view and 53 cm per second at a depth of 18 cm in the apical views. The Nyquist limit was more appropriately set at 62 cm per second at a depth of 15 cm later in the study. The color gain was somewhat increased during this study but this study was clearly evaluable.

.... The parasternal long-axis view was appropriate for the evaluation of aortic regurgitation during color flow doppler. Therefore, the apical long-axis view was not used for the determination of the severity of aortic regurgitation. Visually, only trace aortic regurgitation was suggested in the parasternal long-axis view. I digitized the cardiac cycles in the parasternal long-axis view in which the aortic regurgitant jet could best be evaluated in the mid portion of diastole. I was able to accurately measure the JH and LVOTH with electronic calipers. The LVOTH was 2.2 cm. I measured the JH in all representative frames. The JH was 0.17 cm at 18:49:16 on the tape. The JH was 0.15 cm at 18:52:12 on the tape. The JH was 0.17 cm at 18:56:23 on the tape. The JH was 0.14 cm at 19:08:26 on the tape. The JH was 0.19 cm at 19:11:21 on the tape. The JH was 0.12 cm at 19:36:10 on the tape. The JH Was 0.15 cm at 19:40:018 on the tape. At worst, the JH/LVOTH was less than 9%. The JH/LVOTH ratio never reached 10%. Therefore, this study was diagnostic of trace aortic regurgitation. I reviewed the sonographer's JH measurements on the tape. These measurements were inaccurate as they were further down into the left ventricular outflow tract as opposed to immediately below the aortic valve. The measurements of JH of 0.235 cm at 0:18:56 on the tape and 0.374 cm at 0:19:11:21 on the tape are the same

inaccurate measurements documented by Dr. Podet in his declaration.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor did not adequately explain how claimant's echocardiogram was not performed in accordance with the usual standards of care. Claimant also asserts that the Nyquist limit was in the range recommended by the American Society of Echocardiography and that the Nyquist levels were "unchallenged in the Show Cause Record." In addition, claimant contends that Dr. Vigilante erred by failing to consider aortic regurgitation in the apical view. Mr. Herman also argues that Dr. Vigilante did not properly apply the reasonable medical basis standard and that his attesting physician's representation should be accepted unless it is extreme or excessive. In addition, Mr. Herman asserts that Dr. Vigilante did not provide the exact amount of aortic insufficiency he found during his review of claimant's echocardiogram and suggests that Dr. Vigilante mentioned, but did not consider, inter-reader variability. Finally, claimant contends that Dr. Podet correctly measured Mr. Herman's JH into the LVOT rather than immediately below the aortic valve.

After reviewing the entire Show Cause Record, we find the claimant's arguments are without merit. Contrary to claimant's assertion, the opinion of his expert, Dr. Podet, does not provide a reasonable medical basis for his claim. We are required to apply the standards delineated in the Settlement

Agreement and Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating the echocardiogram setting; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Parmar reviewed claimant's echocardiogram and determined that it demonstrated only trace aortic regurgitation. Dr. Podet identified a number of times and measurements on the tape he contended demonstrated mild aortic regurgitation. Dr. Parmar reviewed these time frames and observed that they were "overestimated." Dr. Vigilante also reviewed claimant's echocardiogram and determined that it did not demonstrate mild aortic regurgitation. Dr. Vigilante obtained JH and LVOTH measurements representative of the aortic regurgitation on the study and determined that "[a]t worst, the JH/LVOTH ratio was

less than 9%. The JH/LVOTH ratio never reached 10%."[10] Dr. Vigilante also reviewed the specific frames referenced by Dr. Podet and determined they "were inaccurate as they were further down into the left ventricular outflow tract as opposed to immediately below the aortic valve."[11] Such unacceptable practices by claimant's cardiologists cannot provide a reasonable medical basis for the resulting Green Form representation that claimant suffered from at least mild aortic regurgitation.

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that he had mild aortic

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10. We reject claimant's argument that he may rely on the apical long-axis view for the determination of his level of aortic regurgitation. Contrary to his claim, the Settlement Agreement specifically requires that aortic regurgitation be measured "in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable)." Settlement Agreement § I.22. As claimant concedes the parasternal long-axis view is available, this argument is without merit.

11. Claimant's argument that Dr. Podet properly measured Mr. Herman's JH is not supported by the documents he cited. First, the quotation from Singh that "[aortic regurgitation] was considered to be present if ... signals ... were seen originating from the aortic valve and spreading into the left ventricle during diastole," is not inconsistent with the findings of the auditing cardiologist or the Technical Advisor. In fact, each of them found aortic regurgitation. This statement does not, as claimant suggests, require that measurement of aortic regurgitation extend into the left ventricle. Second, the quotation from the American Society of Echocardiography that "[t]he preferred assessment is based on the proximal jet width ... immediately below the aortic valve," is entirely consistent with Dr. Vigilante's determination that Dr. Podet relied on measurements that overestimated claimant's JH because "they were [taken] further down into the left ventricular outflow tract as opposed to immediately below the aortic valve."

regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist and the Technical Advisor determined that claimant's echocardiogram demonstrated a JH/LVOTH ratio of less than 10%. Adopting claimant's argument regarding inter-reader variability would allow a claimant without the requisite level of aortic regurgitation to recover benefits and would render meaningless this critical provision of the Settlement Agreement.[12]

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Mr. Herman's claim for Matrix A, Level III

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12. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "An echocardiographer could not reasonably conclude that mild aortic regurgitation was present on this study when appropriate quantitative methods are used to measure the JH even taking into account inter-reader variability." Claimant's contention that he cannot determine whether Dr. Vigilante actually considered inter-reader variability or simply mentioned it because he "fails to give the exact amount of [aortic insufficiency] found on the study" is baseless. To the contrary, Dr. Vigilante stated the JH measurements he obtained (0.17 cm, 0.15 cm, 0.14 cm, 0.19 cm, and 0.12 cm) and the LVOTH measurement he obtained (2.2 cm).

benefits and the related derivative claim submitted by his spouse.